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No. 93-1450

In the Supreme Court of the United States

OCTOBER TERM, 1993

CEDARS-SINAI MEDICAL CENTER, ET AL., PETITIONERS

v.

HAZEL O'LEARY, SECRETARY OF ENERGY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly applied the two-part test set forth in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), in concluding that petitioners' challenge to a Department of Energy determination of government patent rights, made pursuant to 42 U.S.C. 5908, was not ripe for adjudication.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A27) is reported at 11 F.3d 1573. The opinion of the district court (Pet. App. B1-B8) is unpublished.

JURISDICTION

The judgment of the court of appeals was entered on December 13, 1993. The petition for a writ of certiorari was filed on March 11, 1994. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. In June, 1983, petitioner Warren S. Grundfest, M.D., conducted an experiment in the field of laser angioplasty at the Argonne National Laboratory, a government-owned facility operated by the University of Chicago under contract with the Department of Energy (DOE), with the participation of Dr. Dieter M. Gruen, an employee of the Argonne facility who had arranged Dr. Grundfest's visit to the facility.[1] Following the experiment, both Dr. Grundfest and Dr. Gruen filed applications to patent the laser angioplasty technique. Ralph Linsker, a third party who took no part in the Argonne experiment, also sought to patent a similar invention. Pet. App. A3-A4, B2-B3.

On August 18, 1987, United States Patent No. 4,686,979, entitled "Excimer Laser Phototherapy for the Dissolution of Abnormal Growth," was issued to the government, as assignee of Dr. Gruen's application. Following the issuance of the patent, petitioner Cedars-Sinai Medical Center (Cedars)—Dr. Grundfest's employer and the assignee of his patent application—initiated an Interference action in the Patent and Trademark Office (PTO) to determine who first invented the laser angioplasty technique.[2] On Sep-

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[1] Laser angioplasty is a technique through which laser energy is used to treat clogged arteries. Pet. App. F22. In the course of the experiment at the Argonne facility, Dr. Gruen made the critical suggestion that the excimer laser be selected from among the many lasers present at the Argonne facility. *Id.* at F27.

[2] An Interference is a quasi-judicial proceeding before the PTO's Board of Patent Appeals and Interferences to deter-

tember 10, 1991, the PTO's Board of Patent Appeals and Interferences (Board) declared (accepted for determinaton) Interference No. 102,459 (the Interference) between Dr. Grundfest, Dr. Gruen, and Linsker.[3] Pet. App. A3-A4, B2-B3.

2. Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, Pub. L. No. 93-577, 88 Stat. 1878, provides *inter alia* that when any invention is made in the course of an arrangement or understanding with the Secretary of Energy (Secretary), and the Secretary determines that the invention was made with a contribution by the government or the use of government facilities, title to the invention shall vest in, and any patents on the invention shall issue to, the United States. 42 U.S.C. 5908 (a) and (m)(2). On December 10, 1991, because of the Interference initiated by petitioners, and pursuant to Section 5908, the DOE rendered and served upon petitioners a Determination that, if in fact it was Dr. Grundfest who invented the laser angioplasty technique, the invention was made in the manner specified in Section 5908 (the Determination). Pet. App. F27-F30. The Determination stated that petitioners had 30 days to request reconsideration of the matter. *Id.* at F29-F30. Petitioners failed to do so. *Id.* at A5.

3. Petitioners subsequently filed suit in the United States District Court for the Central District of Cali-

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mine questions of priority of invention and patentability. See 35 U.S.C. 135; *Western Elec. Co.* v. *Piezo Technology, Inc.*, 860 F.2d 428, 431 (Fed. Cir. 1988).

[3] The Interference action is still pending. A decision by the Board in favor of either Dr. Gruen or Linsker will constitute a rejection of petitioners' patent application. 35 U.S.C. 135.

fornia. Pet. App. F1-F21. Petitioners sought both to have the Determination set aside on various grounds under the Administrative Procedure Act, 5 U.S.C. 701-706, and to have a declaratory judgment rendered on several issues under 28 U.S.C. 2201. Pet. App. F17-F19. The district court, after applying the two-pronged test for ripeness set forth in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), dismissed petitioners' complaint, without prejudice, as unripe. Pet. App. B1-B8.

With respect to the "fitness for judicial resolution" prong of the *Abbott Laboratories* test, the district court concluded that petitioners' suit was premature due to the pending Interference. The court reasoned that if the Board ultimately awards the patent to either Dr. Gruen or Linsker, the Determination would be without consequence.[4] Under the "hardship to the parties" prong of the *Abbott Laboratories* test, the district court concluded that petitioners would suffer no ill effects if a judicial decision were deferred until resolution of the Interference. The district court specifically considered and rejected petitioners' argument that the Determination clouded title to their foreign patents and impaired their ability to license those patents. Pet. App. B6-B7.

4. The court of appeals affirmed. Pet. App. A1-A27. Applying the first prong of the *Abbott Laboratories* ripeness test, the court of appeals agreed with the district court that, with respect to petitioners'

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[4] The court also expressed the view that the Board might resolve the issues raised in the Determination. Pet. App. B6. However, both the Board and the Commissioner of Patents and Trademarks subsequently adopted the position that the Board lacks the authority during an Interference to decide patent ownership questions. *Id.* at A16 n.10, C3, D2-D3, E3.

domestic patent rights, "the effects of the Determination have yet to be felt in any concrete sense" and that "due to the pending Interference, judicial resolution of the issues presented would not in any way alleviate the current cloud" over those rights. Pet. App. A17. The court of appeals concluded, however, that petitioners' case was fit for judicial resolution because the Determination clouded petitioners' foreign patent rights and could adversely affect their ability to license those patents. In this regard, the court noted the Interference was immaterial to petitioners' foreign patent rights.[5] The court of appeals therefore held that the first prong of the *Abbott Laboratories* test was satisfied. Pet. App. A18-A20.

Turning next to the "hardship to the parties" prong of the *Abbott Laboratories* test, the court of appeals determined that petitioners "ha[ve] not demonstrated any immediate harm with respect to its foreign patent rights." Pet. App. A26 n.14. The court of appeals noted that petitioners' complaint and supporting affidavits contained only conclusory statements about its efforts to license its foreign patent rights and that "[c]onclusory statements, standing alone, are insufficient to carry [petitioners'] burden to prove hardship under the second prong of the *Abbott Laboratories* test." *Id.* at A25. Because petitioners failed to satisfy the second prong of the *Abbott Laboratories* test, the court of appeals held that the district court had properly dismissed the case without prejudice as unripe. Pet. App. A27.

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[5] The court of appeals noted that "the issue before the Board is priority of invention, an issue which is irrelevant under the pertinent first-to-file foreign patent laws and which cannot by itself affect the issue of who first *filed* the application for patent." Pet. App. A18.

ARGUMENT

1. Petitioners contend (Pet. 9-15) that the court of appeals misapplied the *Abbott Laboratories* test. In their view, satisfaction of the first prong of that test compels the conclusion that a case is ripe for adjudication and obviates the need to consider the second prong. Petitioners' argument is incorrect.[6]

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[6] Petitioners also suggest (Pet. 10-11) that the courts below should not have employed the *Abbott Laboratories* test at all, on the theory that the test applies only in the context of pre-enforcement challenges to agency regulations. That claim, however, was not considered by either of the courts below. Petitioners have never before questioned the applicability of the *Abbott Laboratories* test (quite the contrary is true, see Pet. C.A. Br. 15-24), and neither of the courts below suggested that the test might be inapplicable here. In any event, although the *Abbott Laboratories* test did arise in the context of preenforcement review of agency regulations, the test has been applied outside of that context. For example, in *Air New Zealand Ltd.* v. *CAB*, 726 F.2d 832 (D.C. Cir. 1984), the court considered an airline's challenge to a proviso contained in an agency order granting the airline authority to provide limited service between Los Angeles, London, and New Zealand. Applying the *Abbott Laboratories* test, then-Judge Scalia, stating that the "doctrine has strong application here," *id.* at 835, determined for the court that the airline's challenge was not ripe. See also *ANR Pipeline Co.* v. *FERC*, 876 F.2d 124, 130-131 (D.C. Cir. 1989) (dismissing as unripe under *Abbott Laboratories* a challenge to a proviso in a certificate authorizing the transportation of imported natural gas).

Petitioners also suggest (Pet. 11-12) that *Abbott Laboratories* is inapplicable here because (1) the Determination was a final agency action and (2) their challenge raises purely legal issues. Those facts, however, do not make the *Abbott Laboratories* test inapplicable. In *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158 (1967), this Court held that a challenge to an agency regulation was not ripe, notwithstanding

a. Assuming *arguendo* that the first prong of the *Abbott Laboratories* test was satisfied in this case, there was no legal error in dismissing the suit as unripe on the basis of the second prong alone. The basic rationale of the ripeness doctrine "is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Laboratories*, 387 U.S. at 148.[7] In *Abbott Laboratories*, which has been described as the "leading discussion of the doctrine," *Pacific Gas & Elec. Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 201 (1983), the Court laid out a two-part test for assessing the ripeness of a legal challenge.[8] Under that test, a court must "evaluate *both* the fitness of the issues for judicial decision *and* the hardship to the parties of withholding court consideration." 387 U.S. at 149 (emphasis added). As this language suggests, a would-be plaintiff must

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the Court's express recognition of the fact that the regulation was a "final agency action" and the suit presented "a purely legal question." *Id.* at 162, 163.

[7] Although it also has a prudential aspect, the doctrine in some of its applications is compelled by the Constitution's "case or controversy" requirement. See *Reno* v. *Catholic Social Servs., Inc.*, 113 S. Ct. 2485, 2495 n.18 (1993); *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 138 (1974).

[8] The *Abbott Laboratories* test was applied in two other cases decided on the same day. See *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158 (1967); *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167 (1967).

satisfy both prongs of the test for a suit to be ripe. See also *id.* at 153 ("Where the legal issue presented is fit for judicial resolution, *and* where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to the courts * * * must be permitted.") (emphasis added); *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158, 164 (1967) ("[T]he test of ripeness, as we have noted, depends *not only* on how adequately a court can deal with the legal issue presented, *but also* on the degree and nature of the regulation's present effect on those seeking relief.") (emphasis added); *Poe* v. *Ullman*, 367 U.S. 497, 508-509 (1961) ("Justiciability * * * is the resultant of many subtle pressures, including the appropriateness of the issues for decision by this Court and the actual hardship to the litigants of denying them the relief sought."); Erwin Chemerinsky, *Federal Jurisdiction* § 2.4, at 108 (1989) ("[T]he Court's decisions seem to indicate that both [ripeness] requirements must be met."). Moreover, in every case in which this Court has applied the *Abbott Laboratories* test and concluded that a dispute was ripe for review—including *Abbott Laboratories* itself—this Court has addressed both the fitness and hardship prongs of the test.[9] If it is true, as petitioners contend, that a dispute is ripe if it satisfies the fitness

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[9] See *Thomas* v. *Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985); *Pacific Gas*, 461 U.S. at 201-203; *EPA* v. *National Crushed Stone Ass'n*, 449 U.S. 64, 72 n.12 (1980); *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167, 170-174 (1967); *Abbott Laboratories*, 387 U.S. at 148-156; see also *Harrison* v. *PPG Indus., Inc.*, 446 U.S. 578, 603 (1980) (Stevens, J., dissenting).

prong alone, the Court's hardship analysis in each of these cases was superfluous.

b. Petitioners argue (Pet. 12-13, 15) that, by dismissing their suit solely on the basis of the second prong of the *Abbott Laboratories* test, the court of appeals utilized an approach contrary to that employed in the D.C. Circuit. There is, however, no such conflict.

The D.C. Circuit generally follows the rule that a plaintiff must satisfy both the fitness and hardship prongs of the *Abbott Laboratories* test and has on numerous occasions dismissed cases on the basis of the hardship prong alone. See *Tenneco Gas* v. *FERC*, 969 F.2d 1187, 1211 (D.C. Cir. 1992) ("Although *Athlone* [*Indus.* v. *Consumer Prods. Safety Comm'n*, 707 F.2d 1485 (D.C. Cir. 1983)] supports the pipeline petitioners as to the fitness of their claim, they still must show that delay in settling the civil penalties issue will cause them to suffer a hardship."); *Public Citizen, Inc.* v. *U.S. Nuclear Regulatory Comm'n*, 940 F.2d 679, 684 (D.C. Cir. 1991) ("[E]ven assuming that the claim is close enough to fitness for review that a showing of hardship would enable us to eke out a ripeness finding, petitioners have not shown any such hardship."); *ANC Pipeline Co.* v. *FERC*, 876 F.2d 124, 131 (D.C. Cir. 1989) ("We may assume without deciding that the issue is fit for judicial review. * * * We can, however, find no hardship to Great Lakes in postponing review."); *Consolidation Coal Co.* v. *Federal Mine Safety & Health Review Comm'n*, 824 F.2d 1071, 1082 (D.C. Cir. 1987) (rejecting the suggestion "that 'fitness for review' alone is always sufficient to make a claim ripe").[10]

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[10] See also *American Fed'n of Gov't Employees* v. *FLRA*, 750 F.2d 143, 144 (D.C. Cir. 1984); *American Trucking*

It is true that, in a narrow category of cases, the D.C. Circuit has dispensed with the hardship test. This exception to the general rule originated in *Eagle-Picher Indus., Inc.* v. *United States EPA*, 759 F.2d 905 (1985). In that case, Eagle-Picher sought to challenge an EPA regulation adopted pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601 *et seq.*, but failed to bring the challenge within 90 days of the regulation's promulgation, as an applicable CERCLA provision required. Eagle-Picher argued that the lateness of its challenge should be excused on the ground that, had it filed suit within the 90-day period, the suit would not have been ripe. The D.C. Circuit disagreed. After concluding that the issue would have been fit for judicial resolution within the 90-day period, the court declared that "[w]e need not proceed in this case to the second prong of the *Abbott Laboratories* test," because "[w]here the first prong of the ripeness test is met *and Congress has emphatically declared a preference for immediate review*, * * * no purpose is served by proceeding to the second prong." 759 F.2d at 918 (emphasis added).[11] The *Eagle-Picher* exception

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Ass'ns v. *ICC*, 747 F.2d 787, 790 (D.C. Cir. 1984); *Tennessee Gas Pipeline Co.* v. *FERC*, 736 F.2d 747, 749 (D.C. Cir. 1984); *South Carolina Elec. & Gas Co.* v. *ICC*, 734 F.2d 1541, 1545 (D.C. Cir. 1984); *Alascom, Inc.* v. *FCC*, 727 F.2d 1212, 1217 (D.C. Cir. 1984); *Air New Zealand Ltd.* v. *CAB*, 726 F.2d 832, 838 (D.C. Cir. 1984); *Baltimore Gas & Elec. Co.* v. *ICC*, 672 F.2d 146, 149 (D.C. Cir. 1982).

[11] Accord *National Recycling Coalition, Inc.* v. *Browner*, 984 F.2d 1243, 1249 (D.C. Cir. 1993); *Her Majesty the Queen* v. *United States EPA*, 912 F.2d 1525, 1533 (D.C. Cir. 1990); *National Recycling Coalition, Inc.* v. *Reilly*, 884 F.2d 1431,

plainly does not apply here, since there is nothing in 42 U.S.C. 5908 suggesting that Congress favored immediate challenges to patent right determinations. Petitioners do not contend otherwise.

2. Petitioners also contend (Pet. 15-22) that, assuming they were required to show hardship under the second prong of the *Abbott Laboratories* test, they have done so. That is a fact-specific question that both lower courts have resolved against petitioners. Further review of that factual claim is unwarranted. See, *e.g.*, *Goodman* v. *Lukens Steel Co.*, 482 U.S. 656, 665 (1987); *United States* v. *Doe*, 465 U.S. 605, 614 (1984). In addition, the Federal Circuit, which has exclusive appellate jurisdiction in cases relating to the patent laws, see 28 U.S.C. 1295(a)(1); Pet. App. A7-A8, has particular expertise in the subject matter of this suit. "Because of the unique character of the Federal Circuit," its conclusion in this case that adjudication of petitioners' challenge to the Determination should be withheld pending the outcome of the Interference is "entitled to special deference." *United States* v. *Fausto*, 484 U.S. 439, 464 n.11 (1988) (Stevens, J., dissenting).

3. Petitioners' contention (Pet. 19-21) that their property has been taken without due process is without merit. The district court expressly dismissed petitioners' complaint *without prejudice*. Pet. App. B8. Therefore, they are at complete liberty to refile their complaint at such time as their suit is ripe. It does not deny petitioners due process to postpone review of the Determination pending the outcome of the Interference when there is no evidence of hardship in

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1434 (D.C. Cir. 1989); *Consolidation Coal Co.*, 824 F.2d at 1081.

so doing. Cf. *Thunder Basin Coal Co.* v. *Reich*, 114 S. Ct. 771, 781-782 (1994).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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